1641 #10
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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:	A. Burchell et al.	Examiner:	Not Assigned
Serial No.:	09/972,105	Group Art Unit:	1641
Filed:	October 4, 2001	Docket:	350013-76
Due Date:	August 22, 2002	Date Mailed:	August 21, 2002
Title:	PRENATAL DIAGNOSTIC METHODS		

CERTIFICATE UNDER 37 CFR 1.8: The undersigned hereby certifies that this correspondence is being deposited with the United States Postal Service, as first class mail, with sufficient postage, in an envelope addressed to: Commissioner for Patents, Washington, D.C. 20231, on August 21, 2002.

By: Joy Johnson
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RESPONSE TO RESTRICTION REQUIREMENT

Honorable Commissioner
for Patents
Washington, DC 20231

Dear Sir:

In response to the Restriction Requirement mailed July 22, 2002 (Paper No. 9), Applicant replies as follows:

THE RESTRICTION REQUIREMENT

Restriction to one of the following inventions is required under 35 U.S.C. § 121:

Group I is claims 1, 3-8, and 10-16, drawn to a method of identifying embryonic or fetal red blood cells, classified in Class 435, subclass 63.

Group II is claims 2, 3-7, and 9-16, drawn to a method of isolating embryonic or fetal red blood cells, classified in Class 435, subclass 2.

Group III is claims 17-21, drawn to a method and kit for identifying fetal abnormality via genetic material analysis, classified in Class 435, subclass 6.

Group IV is claim 23, drawn to a means for determining an adult liver component in a cell, classified in Class 531, subclass 380.

The methods of Groups I, II, III and the means of Group IV were stated to be unrelated, because they were stated to have different operations, functions, and effects.

RESPONSE TO THE RESTRICTION REQUIREMENT

Applicants hereby elect the invention of Group II, claims 2, 3-7, and 9-16, drawn to a method of isolating embryonic or fetal red blood cells, for prosecution on the merits, with traverse.

Applicants respectfully request that the restriction requirement either be withdrawn completely, or, in the alternative, modified so that the inventions of Groups I, II, and III are examined on the merits.

The Restriction Requirement is traversed on the following grounds:

Firstly, the Examiner has not met the required burden for demonstrating the necessity for restriction. M.P.E.P. § 803 requires for restriction both: (1) that the inventions are independent or distinct as claimed and (2) that there would exist a "serious burden" on the Examiner if all of the claims were examined together in one application.

These requirements have not been met. Firstly, there is no demonstration that a "serious burden" on the Examiner would exist. For example, the methods of claim 1 (Group I) and claim 2 (Group 2) both require determining whether or not cells contain or express an adult liver component. Clearly, the relevant art with respect to these two claims, should any such relevant art exist, would largely overlap. This is because relevant art, if it exists, is directed to methods for detecting the content or expression of any such adult liver components such as proteins or enzymes. Typically, publications directed to the purification and properties of such proteins, including enzymes and other proteins such as transporters, disclose the function, properties and occurrence of such proteins, and describe the cellular location of these proteins in particular cell strains or cell types. Thus, the art would be expected to largely overlap.

The same applies to Group IV (claim 23), which again requires determining a liver component. This claim therefore should be examined together with those of Group I and Group II.

Although claims 17-21 (Group III) are directed to identifying a fetal abnormality, they also turn on the detection of the same liver components. Accordingly, the art required to search all of these claims largely, if not completely, overlaps. Therefore, a "serious burden" on the Examiner would not exist if all of these claims were examined in one application.

Additionally, these inventions are related. Applicants respectfully disagree that the inventions are not disclosed as capable of use together. Applicants further disagree that they have different modes of operation, different functions, or different effects. For example, embryonic or fetal red blood cells can be identified using the method of claim 1 and, if appropriate, can then be isolated by the method of claim 2. Thus, at least Groups I and II should be combined. Similarly, the methods for identifying a fetal abnormality of Group III use the methods of identification or isolation of Groups I or II. Thus, again, the methods are capable of use together.

This relatedness applies whether or not detection is done at the DNA level or the protein level. This is because typical publications in this art are directed to both the DNA and the protein sequence. Moreover, the skill of the art has advanced to such a level that it is possible to determine DNA sequences from protein sequences by preparing an appropriate nucleic acid probe based on protein sequences and then isolating the corresponding genomic DNA or messenger RNA. Similarly, if nucleic acid structure is known, it is an easy matter to determine the protein sequence using the standard genetic code.

Thus, these inventions are clearly related and the Examiner is respectfully requested to withdraw the Restriction Requirement or modify it as requested.

Applicants do not traverse the Restriction Requirement on the grounds of lack of patentable distinctness. Rather, applicants traverse the Restriction Requirement on the grounds that a sufficient burden to require restriction does not exist and that the inventions are sufficiently related to preclude restriction notwithstanding the existence of patentable distinctness.

In summary, Applicants elect the invention of Group II (claims 2, 3-7, and 9-16) for prosecution on the merits, with traverse. The Restriction Requirement is respectfully

traversed and the Examiner is respectfully requested either to withdraw it or modify it by examining the claims of Groups I, II, and III on the merits.

Respectfully submitted,

Dated: August 21, 2002

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